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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,840	01/17/2001	Barbara A. Zilinskas	13216-73220	8791

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EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,840

Applicant(s)

ZILINSKAS ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Request for continued examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 June 2004 has been entered.

Status of the Claims

2. The Rule 1.132 Declaration of Barbara A Zilinskas is acknowledged.
3. Applicant has cancelled claims 4 and 11-21, and amended claims 1, 3 and 7. Claims 1-3 and 5-10 are pending, and are examined in the instant action.
4. All rejections not addressed below have been withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Oath/Declaration

6. The oath or declaration is defective. It was not executed in accordance with either 37 CFR 1.66 or 1.68. A new oath or declaration in compliance with See 37 CFR 1.52(c). is required. The oath or declaration is defective because: Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-3 and 5-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 3, "the" turfgrass plant, lacks antecedent basis.

In claim 3, "pSB11" and "hybrid vector" lack antecedent basis.

Claims 1-3 and 5-10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: inoculation conditions (claim 1, line 6), and culturing conditions (claim 1, line 11).

Claim Rejections - 35 USC § 112, first paragraph

9. Claims 1-3 and 5-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The phrase "culturing organogenic" are not supported by the originally filed specification or claims. Applicant is invited to point out the page and line number in the specification where support for these phrases can be found. Absent such support, Applicant is required to cancel the new matter in response to this Office Action.

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10. Claims 1-3 and 5-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record in the Office Action of 3 January 2003 and 24 September 2003, and repeated in part below.

- *The amount of guidance given, and the presence of working examples.* The physiological art in general is acknowledged to be unpredictable (MPEP 2164.03). Applicant provides three examples: Example 2, of Agrobacterium mediated transformation of Creeping Bentgrass with superbinary plasmid pSB111SH. Example 3, of Agrobacterium mediated transformation of Tall Fescue with superbinary plasmid pSB111SH. Example 4, Agrobacterium mediated transformation of Velvet Bentgrass with superbinary plasmid pSB111SH. Applicant gives detailed information about bacterial and plant media which could be used, and goes through a series of steps, beginning with production of callus from seed, and followed by steps which could result in the production of transgenic turfgrass tissue or plants. However, Applicant gives no guidance about which protocols, which media and which steps, if any, result is the production of transgenic turfgrass plants. While working examples are not required, guidance as to what protocols, what conditions, what starting materials, and which combinations of these are required, with a reasonable expectation of success. Lacking such guidance, one skilled in the art would need to do random trial and error experimentation, which would require undue experimentation to make and/or use the claimed invention.

According to Applicant, turfgrass plants are recalcitrant to Agrobacterium transformation (specification p. 1, lines 24-28). Therefore, even greater guidance is required for enablement than otherwise. The specification can provide clarification of elements which are known to one skilled in the art, *essential steps and conditions not known to one of ordinary skill in the art are unpredictable*, and must be recited in the claims.

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The claims are drawn to inoculating with *Agrobacterium* ... and culturing the inoculated tissue under conditions the enable the *Agrobacterium* to transform the tissue (Claim 1, lines 6-14).

No information is given in the claims re the conditions of inoculating, culturing and selectively culturing. The claims are silent on *Agrobacterium* coculture conditions as well as regeneration conditions, about light or dark conditions, plant hormones, species, treatment duration, and concentrations.

Applicant traverses saying primarily (Response, p.5) that the specification teaches certain factors believed to be important to the success of transforming turfgrass, namely the use of strong monocot promoters, the use of strong *vir* genes, and the use of stating material that produced friable regenerable callus, and that amended claim 1 recites each of these factors. Applicant's traversal is unpersuasive. Amended claim 1 is drawn to any turfgrass, any monocot promoter (line 10) and any virulence gene from the plasmid psB1 or pSB4.

Furthermore, whereas Applicant 's specification "teaches certain factors believed to be important to the success of transforming turfgrass, namely the use of strong monocot promoters, the sure of strong *vir* genes, and the use of stating material that produced friable regenerable callus", Applicant does not state that they have **knowledge of** all the relevant factors responsible for a successful outcome. In accord with the scientific method, in order to be predictable, all variables need to be identified, then each variable must be manipulated (or controlled) to determine the effect of that

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variable on the experimental system, thereby determining the relevance of the variable. When all the relevant variable of the experimental system are determined and demonstrated able to totally predict the results an given manipulation, then the system is said to be predictable. Applicant has set forth (specification, p. 1, lines 24-28) that the Agrobacterium/ turfgrass system is recalcitrant, meaning refractory and unpredictable.

No information is given in the claims re the conditions of inoculating, culturing and selectively culturing. The claims are silent on Agrobacterium coculture conditions as well as regeneration conditions, about light or dark conditions, plant hormones, media components, treatment duration, and concentrations.

Applicant asserts that Examiner stated in the interview of 27 February 2004 that a §1.132 Declaration would overcome the rejections.

Applicant's traversal is unpersuasive. Various hypothetical situations were discussed. Examiner stated a § 1.132 Declaration would be considered, however that without having the specific § 1.132 Declaration to examine, no decision was possible.

The Rule 1.132 Declaration of Barbara A Zilinskas having been carefully read, thoroughly considered, is deemed persuasive in part, and unpersuasive in part. Zilinskas (§ 11) discusses Example 2 of the specification, and "attests that transformed turfgrass were obtained". Zilinskas gives specific numbers and details of the Agrobacterium transformation and regeneration of creeping bentgrass. Zilinskas further describes Agrobacterium transformation and regeneration of tall fescue (Example 3) and of Agrobacterium transformation and regeneration of Velvet Bentgrass (Example 4). Clearly, this declaration is persuasive in affirming Applicant's exemplification of the

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method taught in the specification (pages 24-31) to produce *Agrobacterium* mediated transformation of turfgrass and production of transgenic plants using this method.

Zilinskas's Declaration is however unpersuasive because the Declaration is not commensurate with the scope of the claims. Amended claim 1 is drawn to any turfgrass, any monocot promoter (line 10) any virulence gene from the plasmid psB1 or pSB4, any inoculation conditions, any culture (co-culture) conditions, any selectively culturing conditions and to use of any and all antibiotics.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 1-3 and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stalker, US 4,810,648, issued March 7, 1989, in view of Lee, et. al. , (US 5, 948, 956, issued 7 September 1999, filed 16 October 1997 and applicant's admitted state of the prior art.

Stalker teaches the production of transgenic turfgrass (col 6, lines 65-69) by providing regenerable callus tissue (col 6, line 69), inoculating the tissue with *Agrobacterium* (col 21, lines 43-45) having a heterologous DNA construct linked to a promoter from a monocot species (col 6, lines 38-42) and a antibiotic resistance selectable marker (col 19, lines 55-58), culturing under conditions to enable the *Agrobacterium* to transform cells of the tissue (col 21, line 36-55), *Agrobacterium*

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virulence genes, selectively culturing on antibiotic (col 22, lines 63-65), and producing transgenic turfgrass (col 6, lines 63 – col 7, line 2).

Stalker does not teach the virulence genes from pSN1 or pSB4, the maize ubiquitin promoters, rice actin promoters, maize Adh 1 promoters, rice or maize tubulin promoters and or alfalfa Histone 3 promoters, or the genes encoding glucose oxidase, citrate synthase, a gene encoding a delta-9 desaturase, a gene encoding a delta-11 desaturase, a plant homolog of neutrophil NADPH oxidase, a gene encoding bacteriopsin from *H. halobium* and a gene encoding a pokeweed antiviral protein .

Lee, et. al. teach the use of rice actin gene promoter (column 19, lines 5-6), production of transgenic turfgrass (Tables 1 and 2, columns 11-12) by providing a node segment of a stem (column 6, line 69), *Agrobacterium*-mediated gene transfer (column 6, lines 43-45) having a heterologous DNA construct linked to a promoter from a monocot species (col 6, lines 38-42) and a antibiotic resistance selectable marker (col 19, lines 55-58), culturing under conditions to enable the *Agrobacterium* to transform cells of the tissue (col 21, line 36-55), selectively culturing on antibiotic (col 22, lines 63-65), and producing transgenic turfgrass (col 6, lines 63 – col 7, line 2).

Applicant's admitted prior art (specification p. 12, lines 23-30, and p. 19, lines 3-30), teaches the availability of virulence genes of pBS1 and pSB4, the availability of genes encoding glucose oxidase, citrate synthase, a gene encoding a delta-9 desaturase, a gene encoding a delta-11 desaturase, a plant homolog of neutrophil NADPH oxidase, a gene encoding bacteriopsin from *H. halobium* and a gene encoding

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a pokeweed antiviral protein, as well as the use of these genes in transgenic plants (p. 19).

Given the recognition of one of ordinary skill in the art of the value of producing transgenic turfgrass having the properties of pathogen resistance and stress resistance, one of ordinary skill in the art would have been motivated to substitute the genes of applicant's admitted prior art to improve the pathogen and stress resistance of transgenic turfgrass, with a reasonable expectation of success, without undue experimentation. Thus the claimed invention would have been prima facie obvious as a whole to one of ordinary skill in the art at the time it was made, especially in the absence of evidence to the contrary.

Remarks

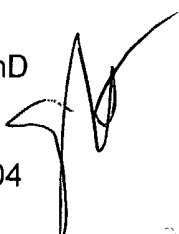
13. No claim is allowed, given the prior art of record.

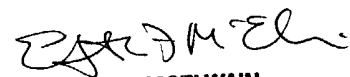
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia Helmer PhD
Patent Examiner
Art Group 1638
September 20, 2004




ELIZABETH MCELWAIN
PRIMARY EXAMINER